Senate Bill 205

By: Senators Thomas of the 54th, Balfour of the 9th, Henson of the 41st, Wiles of the 37th, Unterman of the 45th and others

AS PASSED

AN ACT

To amend Article 5 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to prescription drugs, so as to provide that the use of the mails or other common carriers to sell, distribute, and deliver a prescription drug directly to a patient under certain circumstances shall not be considered grounds for sanctioning the license of a pharmacist; to amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, so as to enact the "Prescription Medication Integrity Act"; to provide for a short title; to provide for definitions; to provide for pedigrees for prescription drugs; to provide for contingent effectiveness; to provide for enforcement; to provide for prohibited acts; to provide for penalties; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Article 5 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to prescription drugs, is amended in Code Section 26-4-60, relating to grounds for suspension, revocation, or refusal to grant licenses by the State Board of Pharmacy, by revising paragraph (11) of subsection (a) as follows:

"(11) Regularly employing the mails or other common carriers to sell, distribute, and deliver a drug which requires a prescription directly to a patient; provided, however, that this provision shall not prohibit the use of the mails or other common carriers to sell, distribute, and deliver a prescription drug directly to:

(A) A patient or directly to a patient's guardian or caregiver or a physician or physician acting as the patient's agent for whom the prescription drug was prescribed if:

(i) Such prescription drugs are prescribed for complex chronic, terminal, or rare conditions;

(ii) Such prescription drugs require special administration, comprehensive patient training, or the provision of supplies and medical devices or have unique patient compliance and safety monitoring requirements;

(iii) Due to the prescription drug´s high monetary cost, short shelf life, special manufacturer specified packaging and shipping requirements or instructions which require temperature sensitive storage and handling, limited availability or distribution, or other factors, the drugs are not carried in the regular inventories of retail pharmacies such that the drugs could be immediately dispensed to multiple retail walk-in patients;

(iv) Such prescription drug has an annual retail value to the patient of more than $10,000.00;

(v) The patient receiving the prescription drug consents to the delivery of the prescription drug via expedited overnight common carrier and designates the specialty pharmacy to receive the prescription drug on his or her behalf;

(vi) The specialty pharmacy utilizes, as appropriate and in accordance with standards of the manufacturer, United States Pharmacopeia, and Federal Drug Administration and other standards adopted by the State Board of Pharmacy, temperature tags, time temperature strips, insulated packaging, or a combination of these; and

(vii) The specialty pharmacy establishes and notifies the enrollee of its policies and procedures to address instances in which medications do not arrive in a timely manner or in which they have been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs; or

(B) An institution or to sell, distribute, or deliver prescription drug refills, upon his or her request, to an enrollee in a health benefits plan of a group model health maintenance organization or its affiliates by a pharmacy which is operated by that same group model health maintenance organization and licensed under Code Section 26-4-110. Any pharmacy using the mails or other common carriers to dispense prescriptions pursuant to this paragraph shall comply with the following conditions:

(i) The pharmacy shall provide an electronic, telephonic, or written communications mechanism which reasonably determines whether the medications distributed by the mails or other common carriers have been received by the enrollee and through which a pharmacist employed by the group model health maintenance organization or a pharmacy intern under his or her direct supervision is enabled to offer counseling to the enrollee as authorized by and in accordance with his or her obligations under Code Section 26-4-85, unless the enrollee refuses such consultation or counseling pursuant to subsection (e) of such Code section. In addition, the enrollee shall receive information indicating what he or she should do if the integrity of the packaging or medication has been compromised during shipment;

(ii) In accordance with clinical and professional standards, the State Board of Pharmacy shall promulgate a list of medications which may not be delivered by the mails or other common carriers. However, until such list is promulgated, the group model health maintenance organization shall not deliver by use of the mails or other common carriers Class II controlled substance medications, medications which require refrigeration, chemotherapy medications deemed by the federal Environmental Protection Agency as dangerous, medications in suppository form, and other medications which, in the professional opinion of the dispensing pharmacist, may be clinically compromised by distribution through the mail or other common carriers;

(iii) The pharmacy shall utilize, as appropriate and in accordance with standards of the manufacturer, United States Pharmacopeia, and Federal Drug Administration and other standards adopted by the State Board of Pharmacy, temperature tags, time temperature strips, insulated packaging, or a combination of these; and

(iv) The pharmacy shall establish and notify the enrollee of its policies and procedures to address instances in which medications do not arrive in a timely manner or in which they have been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs.

For purposes of subparagraph (B) of this paragraph, the term 'group model health maintenance organization' means a health maintenance organization that has an exclusive contract with a medical group practice to provide or arrange for the provision of substantially all physician services to enrollees in health benefits plans of the health maintenance organization;"

SECTION 2.

Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, is amended by inserting a new article at the end of such chapter to read as follows:

"ARTICLE 12

26-4-200.

This article shall be known and may be cited as the 'Prescription Medication Integrity Act.'

26-4-201.

As used in this article, the term:

(1) 'Authenticate' means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(2) 'Authorized distributor of record' means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer´s prescription drugs.

(3) 'Board' means the State Board of Pharmacy.

(4) 'Broker' has the same meaning as a third party logistics provider.

(5) 'Chain pharmacy warehouse' means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership or control.

(6) 'Co-licensed pharmaceutical products' means pharmaceutical products:

(A) That have been approved by the federal Food and Drug Administration; and

(B) Concerning which two or more parties have the right to engage in a business activity or occupation concerning the pharmaceutical products.

(7) 'Co-licensee' means a party to a co-licensed pharmaceutical product.

(8) 'Distribute' means to deliver a drug or device other than by administering or dispensing.

(9) 'Drop shipment arrangement' means the physical shipment of a prescription from a manufacturer, that manufacturer´s co-licensee, that manufacturer´s third-party logistics provider, or that manufacturer´s authorized distributor of record directly to a chain pharmacy warehouse, pharmacy buying cooperative warehouse, pharmacy, or other persons authorized under law to dispense or administer prescription drugs but wherein the sale and title for the prescription drug passes between a wholesale drug distributor and the party that directly receives the prescription drug. In order to be considered part of the normal distribution channel and participate in a drop shipment as described in this paragraph, the wholesale drug distributor must be an authorized distributor of record.

(10) 'Facility' means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

(11) 'Manufacturer' means a person licensed or approved by the federal Food and Drug Administration ('FDA') to engage in the manufacture of drugs or devices, consistent with the FDA definition of 'manufacturer' under the regulations and interpreted guidances implementing the Prescription Drug Marketing Act.

(12) 'Manufacturer´s exclusive distributor' means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services for a

manufacturer and takes title to that manufacturer´s prescription drug. To be considered part of the normal distribution channel, a manufacturer´s exclusive distribution must be an authorized distributor of record.

(13) 'Normal distribution channel' means a chain of custody for a prescription drug, excluding all devices and veterinary prescription drugs, that goes directly or by drop shipment from a manufacturer of the prescription drug, or from that manufacturer to that manufacturer´s co-licensed partner, or from that manufacturer to that manufacturer´s third-party logistics provider, or from that manufacturer to that manufacturer´s exclusive distributor, to:

(A) Either a pharmacy or to other designated persons authorized by law to dispense or administer such drug;

(B) An authorized distributor or record, and then to either a pharmacy, or to other designated persons authorized by law to dispense or administer such drug;

(C) An authorized distributor of record to one other authorized distributor of record to an office based health care practitioner authorized by law to dispense or administer such drug to a patient;

(D) An authorized distributor of record to a pharmacy warehouse or other entity that redistributes by intracompany sale to a pharmacy or other designated persons authorized to dispense or administer the drug;

(E) A pharmacy warehouse or other entity that redistributes by intracompany sale to a pharmacy or other designated persons authorized to dispense or administer the drug; or

(F) Another entity as prescribed by the board´s regulations.

(14) 'Ongoing relationship' means an association that exists when a wholesale drug distributor, including any member of its affiliated group, as defined in Section 1504 of the Internal Revenue Code, of which the wholesale drug distributor is a member:

(A) Is listed on the manufacturer´s list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis; or

(B) Has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship.

(15) 'Pedigree' means a document or electronic file containing information that records each distribution of any given prescription drug.

(16) 'Pharmacy buying cooperative warehouse' means a permanent physical location that acts as a central warehouse for drugs and from which sales of drugs are made to a group of pharmacies that are member owners of the buying cooperative operating the

warehouse. Pharmacy buying cooperative warehouses must be licensed as wholesale distributors.

(17) 'Prescription drug' means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by federal law (including federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the federal Food, Drug and Cosmetic Act ('FFDCA').

(18) 'Repackage' means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug; provided, however, that this shall not apply to pharmacists in the dispensing of prescription drugs to the patient.

(19) 'Repackager' means a person who repackages.

(20) 'Third-party logistics provider' means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer but does not take title to a drug or have general responsibility to direct the sale or other disposition of the drug. To be considered part of the normal distribution channel, a third party logistics provider must be an authorized distributor of record.

(21) 'Wholesale distributor' means any person engaged in wholesale distribution of drugs, including but not limited to repackagers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers´ and distributors´ warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail and hospital pharmacies and chain pharmacy warehouses that conduct wholesale distributions. This term shall not include manufacturers.

(22) 'Wholesale distribution' shall not include:

(A) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership or control of a corporate entity, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(B) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons including transfers of a prescription drug from retail pharmacy to retail pharmacy, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(C) The distribution of prescription drug samples by manufacturers´ representatives;

(D) Prescription drug returns when conducted by a retail pharmacy or chain pharmacy warehouse, by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. Section 203.23, or by any designated persons authorized by law to dispense or administer the prescription drug except in cases where a pedigree is already required under the provisions of this article, in which case any return of that prescription drug to a wholesaler or manufacturer shall be subject to the provisions of Code Section 26-4-202;

(E) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(F) Retail pharmacies´ delivery of prescription drugs to a patient or patient´s agent pursuant to the lawful order of a licensed practitioner;

(G) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier´s usual course of business of transporting prescription drugs, and such common carrier does not store, warehouse, or take legal ownership of the prescription drug;

(H) The sale or transfer from a retail pharmacy, pharmacy buying cooperative warehouse, or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, originating wholesale distributor, or to a third party returns processor, to the extent permitted by federal rule, regulation, or law; or

(I) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

26-4-202.

(a)(1) Each person who is engaged in wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave or have ever left the normal distribution channel in accordance with rules and regulations adopted by the board.

(2) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this Code section only if the retail pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(3) The board shall conduct a study to be completed no later than July 1, 2009, which shall include consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. Based on the results of the study, the board shall establish a mandated implementation date for electronic pedigrees which shall be no sooner than December 31, 2011, and may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply; provided, however, that no provision of this article shall be effective until such time as the General Assembly appropriates reasonable funds for administration of this subsection. Effective at a date established by the board, pedigrees may be implemented through an approved and readily available system based on electronic track and trace pedigree technology. This electronic tracking system will be deemed to be readily available for use on a wide scale across the entire pharmaceutical supply chain which includes manufacturers, wholesale distributors, and pharmacies. Consideration must be given to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product.

(b) Each person in possession of a pedigree for a prescription drug who is engaged in the wholesale distribution of a prescription drug, including repackagers but excluding the original manufacturer of the finished form of the prescription drug and any entity engaged in the activities listed in paragraph (9) of Code Section 26-4-201, and who attempts to further distribute that prescription drug shall affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(c) The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, to acquisition and sale by any wholesale distributor or repackager, and to final sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the pedigree shall include:

(1) The name, address, telephone number, and, if available, e-mail address of each owner of the prescription drug and each wholesale distributor of the prescription drug;

(2) The name and address of each location from which the prescription drug was shipped, if different from the owner´s;

(3) Transaction dates;

(4) Certification that each recipient, excluding retail or hospital pharmacies, has authenticated the pedigree;

(5) The name of the prescription drug;

(6) Dosage form and strength of the prescription drug;

(7) Size of the container;

(8) Number of containers;

(9) Lot number of the prescription drug; and

(10) The name of the manufacturer of the finished dosage form.

(d) Each pedigree shall be:

(1) Maintained by the wholesale distributor at its licensed location, unless given written authorization from the board to do otherwise, for three years from the date of sale or transfer; and

(2) Available for inspection, copying, or use at the licensed location upon a verbal request by the board or its designee.

(e) The board shall adopt rules and regulations, including a standard form, relating to the requirements of this article no later than 90 days after the effective date of this article.

(f) Pharmacies licensed pursuant to this chapter shall not be required to possess or maintain any pedigree issued pursuant to this Code section.

26-4-203.

(a) If the board finds that there is a reasonable probability that:

(1) A wholesale distributor, other than a manufacturer, has:

(A) Violated a provision of this article; or

(B) Falsified a pedigree, provided a falsified pedigree, or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;

(2) The prescription drug at issue in subparagraph (B) of paragraph (1) of this subsection could cause serious, adverse health consequences or death; and

(3) Other procedures would result in unreasonable delay,

the board shall issue an order requiring the appropriate person including the distributors or retailers of the prescription drug to immediately cease distribution of the prescription drug in or to this state.

(b) An order under subsection (a) of this Code section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten calendar

days after the date of the issuance of the order, on the actions required by the order. If, after such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

26-4-204.

It shall be unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

(1) Selling, distributing, or transferring a prescription drug to a person that is not authorized to receive the prescription drug under the law of the jurisdiction in which the person receives the prescription drug;

(2) Failing to maintain or provide pedigrees as required by the board;

(3) Failing to obtain, transfer, or authenticate a pedigree as required by the board;

(4) Providing the board or any of its representatives or any federal official with false or fraudulent records, including, but not limited to falsified pedigrees, or making false or fraudulent statements regarding any matter within the provisions of this article;

(5) Obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug; and

(6) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the Food and Drug Administration, the manufacturing, repackaging, selling, transferring, delivering, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution.

26-4-205.

(a) Notwithstanding Code Section 26-4-115, any person who engages without knowledge in the wholesale distribution of prescription drugs, including providing a falsified pedigree or other records, in violation of this article may be fined not more than $10,000.00.

(b) If a person engages in wholesale distribution of prescription drugs in violation of this article, including providing a falsified pedigree or other records, and acts in a grossly negligent manner in violation of this article, the person may be punished by imprisonment for not more than 15 years, fined not more than $50,000.00, or both.

(c) Notwithstanding Code Section 26-4-115, any person who knowingly engages in wholesale distribution of prescription drugs in violation of this article, including providing

a falsified pedigree or other records, shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not more than 25 years, by fine not to exceed $500,000.00, or both."

SECTION 3.

All laws and parts of laws in conflict with this Act are repealed.